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UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte MARK MODELL and ZE'EV HED

Appeal 2008-4303
Application 09/841,325
Technology Center 3700

Decided: October 29, 2008

Before ERIC GRIMES, JAY P. LUCAS, and CAROLYN D. THOMAS,
Administrative Patent Judges.

GRIMES, *Administrative Patent Judge.*

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method and apparatus for internal visual analysis of a patient, which the Examiner has rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

Claims 105-111, 113, 115-119, 121-126, 148, 150, 152-156, 159, 160, 162-168, 170, and 171 are pending and on appeal (Appeal Br. 2). The claims subject to each rejection have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claims 105 and 152 are representative and read as follows:

105. A method of sequentially scanning a plurality of substantially non-overlapping regions of an internal biological sample, the method comprising the steps of:

sequentially illuminating said plurality of substantially non-overlapping regions of said sample with electromagnetic radiation using illuminating optics, said sample not surgically exposed; and

collecting electromagnetic radiation emanating from said regions of said sample using collecting optics, wherein a disposable device for use with a single patient is positioned to protect said patient during said scanning.

152. An apparatus for sequentially scanning a plurality of substantially non-overlapping regions of an internal biological sample, the apparatus comprising:

illuminating optics for sequentially illuminating said plurality of substantially non-overlapping regions of said sample with electromagnetic radiation, said sample not surgically exposed;

collecting optics for collecting electromagnetic radiation emanating from said regions of said sample; and

a disposable device for use with a single patient, said disposable device configured to protect said patient during said scanning.

The claims stand rejected as follows:

- Claims 105-107, 109, 110, 115, 125, 126, 152-156, 159, 160, 165-167, 170, and 171 under 35 U.S.C. § 103(a) as obvious in view of Zavislan¹

¹ Zavislan, U.S. Patent 6,424,852 B1, issued Jul. 23, 2002.

and any of Furler,² Saab,³ or Choi;⁴

- Claims 108, 111, 113, 118, 119, 121, 123, 148, 150, 162, and 168 under 35 U.S.C. § 103(a) as obvious in view of Zavislan, any of Furler, Saab, or Choi, and Kittrell;⁵ and

- Claims 116, 117, 122, 124, 163, and 164 under 35 U.S.C. § 103(a) as obvious in view of Zavislan, any of Furler, Saab, or Choi, Kittrell, and Raz.⁶

OBVIOUSNESS

Issue

Most of the claims, including both of the pending independent claims (105 and 152) stand rejected as obvious in view of Zavislan and any of Furler, Saab, or Choi. The Examiner finds that Zavislan teaches a method and apparatus meeting all of the claim limitations except for “the use of a disposable device to protect the patient” (Answer 3). The Examiner finds that the missing limitation is taught by Furler, Saab, or Choi, and concludes that it would have been obvious to modify Zavislan to include “a disposable device such as a sheath in order to protect the patient from possible contamination” (*id.*).

Appellants contend that Zavislan does not teach scanning “an internal biological sample, . . . said sample not surgically exposed,” as recited in

² Furler et al., U.S. Patent 4,362,166, issued Dec. 7 1982.

³ Saab, U.S. Patent 5,337,734, issued Aug. 16, 1994.

⁴ Choi et al., U.S. Patent 6,115, 523, issued Sep. 5, 2000.

⁵ Kittrell et al., U.S. Patent 5,199,431, issued Apr. 6, 1993.

⁶ Raz, U.S. Patent 6,210,331 B1, issued Apr. 3, 2001.

claims 105 and 152 (Appeal Br. 5-6) and that none of Furler, Saab, or Choi makes up for this deficiency (*id.* at 7).

The issue with respect to this rejection, therefore, is whether Zavislan teaches an apparatus and method of scanning internal tissue of a patient without surgically exposing it.

Findings of Fact

FF1. Zavislan states that

[s]ystems have been proposed for confocal scanning of skin. . . . These systems have confocal optics which direct light to the patient's skin tissue and image the returned reflected light. Such optics have a limited field of view of the patient's skin tissue, which for example may cover a tissue area less than one millimeter wide.

(Zavislan, col. 1, ll. 21-30.)

FF2. Zavislan states that a "problem with these systems is that motion of the patient during confocal imaging can cause the tissue area being imaged to move relative to the system's confocal optics, . . . making it difficult for the physician to observe dermal structures of interest" (*id.* at col. 1, ll. 30-37).

FF3. Zavislan discloses "an improved system for confocal imaging of tissue having a mechanical structure, such as a platen, brace, or attachment which both supports the confocal imaging optics of the system and applies stress to a limited surface area of the tissue to minimize skin motion during confocal imaging" (*id.* at col. 1, ll. 52-56).

FF4. Zavislan discloses a first embodiment of the system in which an imaging head is coupled to a platen (*id.* at col. 1, l. 62 to col. 2, l. 10) and a

second embodiment in which a brace supports an imaging head (*id.* at col. 2, ll. 11-29).

FF5. “The first embodiment may be used for confocal imaging of skin tissue on the chest or back, while the second embodiment may be used for gross anatomical features, such as the arm or leg” (*id.* at col. 7, ll. 30-33).

FF6. Zavislans discloses a third embodiment of the imaging system comprising “an attachment having an inner window member and a flexible diaphragm member extending radially from the inner member” and a suction mechanism “for creating a vacuum between the attachment and the surface of the skin tissue” to minimize motion while an “imaging head images the stressed skin tissue through the window member” (*id.* at col. 2, ll. 31-40).

FF7. Zavislans discloses that the third embodiment “is provided by a tissue stabilization system **68** which includes an attachment **69”** (*id.* at col. 6, ll. 27-28).

FF8. Zavislans discloses that “[t]he size or diameter of system **68** and its attachment **69** may be appropriately dimensioned for the skin surface area to be confocally imaged through window **72”** (*id.* at col. 6, ll. 45-48).

FF9. Zavislans discloses that “the third embodiment is useful for smaller regions of the skin, particularly where there is no gross anatomical feature, or where the surface of the skin tissue [is] not substantially level, such as the cervix or forehead” (*id.* at col. 7, ll. 34-38).

FF10. Zavislans states that “[i]n the cervix the tissue being imaged is not skin as that term is commonly understood, but represents internal tissue of a patient. Internal tissues, for example, which are surgically exposed, may be stabilized using the invention.” (*Id.* at col. 7, ll. 43-47.)

Discussion

Appellants do not dispute the Examiner's' conclusion that Furler, Saab, or Choi would have made it obvious to modify Zavislan's method and apparatus by adding a disposable device to protect the patient. The only issue on appeal, therefore, is whether Zavislan teaches or would have suggested to those skilled in the art scanning "an internal biological sample, . . . said sample not surgically exposed," as recited in claims 105 and 152.

We agree with the Examiner that Zavislan discloses the disputed limitation, and therefore that the combination of Zavislan and any of Furler, Saab, or Choi supports a *prima facie* case of obviousness. Zavislan expressly discloses that its third embodiment "is useful for smaller regions of the skin . . . , such as the cervix" (FF9), even though the cervix "is not skin as that term is commonly understood, but represents internal tissue of a patient" (FF10).

We agree with the Examiner that, when Zavislan is read as a whole, it would have been understood by those skilled in the art to suggest imaging of cervical tissue using the third embodiment of Zavislan's system, without surgical exposure. First, Zavislan does not expressly state that surgical exposure is required to image the cervix. Second, as those skilled in the art would have understood, the cervix is accessible via a pre-existing body orifice (see, e.g., Figure 17 of the instant Specification⁷). Finally, Zavislan states that confocal optics have a limited field of view and may cover an area "less than one millimeter wide" (FF1) and that the size or diameter of the

⁷ It is beyond reasonable dispute that people were familiar with the human female anatomy well before the instant application was filed.

third embodiment “may be appropriately dimensioned for the skin surface area to be confocally imaged” (FF8).

We agree with the Examiner that, in view of Zavislan’s express suggestion to modify the size of the third embodiment system as needed for a given target area and the small size of the area imaged in confocal imaging, those skilled in the art would have understood Zavislan to suggest making the third embodiment small enough that it could be inserted into an existing body orifice to image the cervix without the need for surgical exposure.

Appellants argue that Zavislan states that internal tissues, including the cervix, must be surgically exposed to be imaged using Zavislan’s system (Appeal Br. 6-7). Appellants rely on Zavislan’s statement that “[i]n the cervix the tissue being imaged is not skin as that term is commonly understood, but represents internal tissue of a patient. Internal tissues, for example, which are surgically exposed, may be stabilized using the invention.” (Zavislan, col. 7, ll. 43-47, FF10.) Appellants argue that this statement “clearly indicates that cervical tissue ‘represents internal tissue,’ and that ‘surgically exposed’ internal tissues ‘may be stabilized using the invention’” (Reply Br. 3).

We disagree with Appellants’ interpretation of the reference. While it is true that Zavislan’s statement is somewhat ambiguous, for the reasons discussed above, we conclude that the reference would have been understood to disclose imaging of non-surgically exposed cervical tissue.

Zavislan’s statement that “[i]nternal tissues, for example, which are surgically exposed, may be stabilized using the invention” (Zavislan, col. 7,

ll. 45-47) makes the most sense when it is read to mean internal tissues that *require* surgical exposure in order to be contacted by the disclosed imaging system. That is, Zavislan says that all three embodiments of its system are useful in imaging external tissue (Zavislan, col. 7, ll. 28-30), and the third embodiment is also useful for imaging the cervix, although that's technically internal tissue (*id.* at col. 7, ll. 34-45). Zavislan then goes on to say “[i]nternal tissues, for example, which are surgically exposed, may be stabilized using the invention” (Zavislan, col. 7, ll. 45-47); that is, you can image other internal tissues, too, if you cut the patient open to get at them.

We agree with the Examiner’s interpretation of the reference and find that Zavislan expressly teaches imaging an internal biological sample (cervical tissue) that is not surgically exposed. Since Appellants have not asserted any other error in the Examiner’s rejection, we affirm the rejection of claims 105 and 152 as obvious in view of Zavislan and any of Furler, Saab, or Choi. Claims 106, 107, 109, 110, 115, 125, 126, 153-156, 159, 160, 165-167, 170, and 171 fall with claims 105 and 152 because they were not argued separately. 37 C.F.R. § 41.37(c)(1)(vii).

Claims 108, 111, 113, 118, 119, 121, 123, 148, 150, 162, and 168 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Zavislan, any of Furler, Saab, or Choi, and Kittrell. Claims 116, 117, 122, 124, 163, and 164 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Zavislan, any of Furler, Saab, or Choi, Kittrell, and Raz.

Appellants rely on the same argument with respect to these rejections as they relied on with respect to the rejection based on Zavislan and any of Furler, Saab, or Choi (Appeal Br. 8-9). For the reasons discussed above, the

argument is unpersuasive. Since Appellants have asserted no other error in the Examiner's rejections, we affirm the rejection of claims 108, 111, 113, 118, 119, 121, 123, 148, 150, 162, and 168 based on Zavislan, any of Furler, Saab, or Choi, and Kittrell, and the rejection of claims 116, 117, 122, 124, 163, and 164 based on Zavislan, any of Furler, Saab, or Choi, Kittrell, and Raz.

CONCLUSIONS

We affirm all of the rejections on appeal.

AFFIRMED

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